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European Directorate for the
Quality of Medicines & HealthCare



Certification of Substances Division

**Certificate of suitability
No. R1-CEP 2001-166-Rev 00**

1 *Name of the substance:*

2 **GELATIN**

3 Limed Bone Gelatin

4 *Name of holder:*

5 **M/S NARMADA GELATINES LIMITED**

6 Meerganj, Bheraghat Road

7 India-482001 Jabalpur, M.P.

8 *Sites of production:*

9 **M/S NARMADA GELATINES LIMITED**

10 Meerganj, Bheraghat Road

11 India-482001 Jabalpur, M.P.

12 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

13 **R0-CEP 2001-166-REV 02**

14 After examination of the information provided on the origin of raw material(s) and type of
15 tissue(s) used and on the manufacturing process for this substance on the site(s) of
16 production mentioned above, we certify that the substance **GELATIN** meets the criteria
17 described in the current version of the monograph Products with risk of transmitting
18 agents of animal spongiform encephalopathies no.1483 of the European
19 Pharmacopoeia, current edition including supplements.

20 - country (ies) of origin of source materials: **India**
21 - nature of animal tissues used in manufacture: **Bovine bones free from skulls,
22 spinal cord and vertebrae**
23 - manufacturing process: **Alkaline process**

24 The submitted dossier must be updated after any significant change that may alter the
25 quality, safety or efficacy of the substance, or that may alter the risk of transmitting
26 animal spongiform encephalopathy agents.

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: <http://www.edqm.eu>

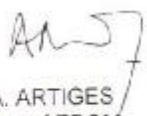
27 Manufacture of the substance shall take place in accordance with a suitable quality
28 assurance system such as GMP and ISO 9001, and in accordance with the dossier
29 submitted.

30 Failure to comply with these provisions will render this certificate void

31 The certificate is valid provided there has been no deterioration in the TSE status of the
32 country(ies) of origin of the source material.

33 This certificate is renewed from 25 April 2007 according to the provisions of Resolution
34 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
35 and any subsequent amendment, and the related guidelines.

36 This certificate has :
37 lines.


Dr. A. ARTIGES
Director of EDQM

Strasbourg, 2 March 2007

DECLARATION OF ACCESS (to be filled in by the certificate holder under their own responsibility)

M/S Narmada Gelatines Limited, as holder of the certificate of suitability

R1-CEP 2001-166-Rev 00 for GELATIN

hereby authorises Sumit Health Care Ltd, Ahmedabad, Rajkot, Gujarat
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): (name of product(s) and marketing number(s), if known)

B. No. - (368)

Qty. - 25000000 (40x50kg)

Mfgdt. - 15.12.08

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature (of the CEP holder):



Address: Tourée Kastner, CS 30026 - F - 67001 Strasbourg (France)
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